

## REMARKS

### I. ELECTION/RESTRICTION

The Examiner states, "this application contains claims drawn to an invention non-elected with traverse in the paper filed March 19, 2003." "Since Applicant has received an action on the merits with originally elected invention, claims 10, 11, 14, 16, 59, and 60 are now withdrawn from consideration as being directed to a non-elected invention." *PTO Paper* dated December 19, 2003.

Applicants have amended independent claim 10 by removing language which caused it to be directed to a non-elected invention. Additionally, claim 10 has been amended to recite specific traits. Support is found in the application as filed. Claims 11, 14, 15, 16, 59 and 60 have been cancelled.

### II. CLAIM OBJECTIONS

#### *A. Claim 45*

The Examiner states, "claim 45 is objected to because the language 'characterized by for' is confusing."

Applicants have amended claim 45 by deleting the word "for" in the phrase "characterized by for", thus alleviating this objection.

### III. CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

#### *A. Claims 45, 46, 54, 55 and 56*

Claims 45, 46, 54, 55 and 56 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner states the amended claim is indefinite because it recites "favorable meat quality traits comprising color, pH level, marbling, and drip loss" but the claim does not set forth what the standard of comparison is for the favorable trait.

Applicants have amended claims 45 and 56 by deleting the recitation "favorable meat quality traits" and replacing this recitation with the specific meat quality traits associated with the

polymorphism. Also, the claims have been amended to recite a standard of comparison for the traits with another animal, i.e., a pig. Further, claims 45 and 56 have been amended to more clearly state that what is being determined is an increased likelihood of a trait occurring in the animal having the disclosed polymorphism. Claims 46-55 have been cancelled, thus alleviating this rejection.

Next, claim 46 was rejected as being indefinite. The Examiner states, "it is not clear how an animal has sequence identity to a polypeptide sequence."

Applicants have cancelled claim 46, thus alleviating this rejection.

Claim 46 was also rejected as being indefinite because "the claim does not set forth what the level is higher than. With respect to 'favorable color scores' the claim does not set forth what makes a color score 'favorable'".

Applicants have cancelled claim 46, thus alleviating this rejection.

The Examiner continues by stating claims 54 and 55 are indefinite because "it is not clear which is being determined, the increased likelihood of the traits or the actual possession of the traits."

Applicants have cancelled claims 54 and 55, thus alleviating this rejection.

Claim 56 was rejected as being indefinite over the recitations "genotype" and "favorable meat quality traits comprising color, pH level, marbling, and drip loss". The Examiner states it is not clear how these traits are favorable and the claim does not set forth what the standard of comparison is for the favorable traits.

Applicants have amended claim 56 by deleting the recitation "genotype" and by deleting the recitation "favorable meat quality traits" and replacing this recitation with the specific meat quality traits associated with the polymorphism. Further, claim 56 has been amended to more clearly recite a standard of comparison for the traits.

#### IV. CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

##### A. *Claims 45, 46, 54, 55 and 56*

Claims 45, 46, 54, 55 and 56 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for pigs does not reasonably provide enablement for any animal. *Id.* at page 9.

Applicants have amended claims 45 and 56 to read on "pigs", and not "animals", thus alleviating this rejection. Claims 46-55 have been cancelled, thus alleviating this rejection.

V. CLAIM REJECTIONS - 35 U.S.C. § 102

A. *Claims 45, 46, 54, and 55*

Claims 45, 46, 54, and 55 were rejected under 35 U.S.C. § 102(a) or 102(b) as being anticipated by Milan et al. (*Science*, 19 May 2000, Vol. 288, pp. 1248-1251).

Applicants have cancelled claims 46, 54 and 55, thus alleviating this rejection, with respect to these claims.

Applicants respectfully submit that in view of the amendments made to claim 45, Applicants are entitled to priority to its Provisional Application Serial No. 60/231,045, filed on September 8, 2000. This makes Milan less than one year before Applicants' priority date and thus Applicants antedating declaration may remove it as a reference. Applicants also claim priority to Provisional Application Serial No. 60/260,239, filed January 8, 2001 and Provisional Application Serial No. 60/299,111, filed June 18, 2001.

Applicants have amended claim 45 to recite the traits associated with the polymorphism which is supported by Applicants priority documents. Specifically, the polymorphism is the I199 allele with the T30-G52 alleles in SEQ ID NO:2.

Applicants disclose in Provisional Application Serial No. 60/231,045 starting at page 2, last paragraph and going onto page 3, that "the different marker genotypes of PRKAG3-199 are the result of a polymorphism within the PRKAG3 gene that results in a guanine to adenine transition at position 1845 (codon 199) resulting in an amino acid valine to isoleucine of the gene. Applicants state the polymorphism can be used alone or in combination. (See page 29- "Results"). On page 20, it is stated "animals having either or both of these alleles potentially

produce meat of the highest technical quality in terms of color, pH, and drip loss. On page 22, using the marker test for the 199 allele, Applicants have found that the allele to be associated with higher pH. On pages 24-25 is an association analysis between the marker and meat quality traits (color and pH) in F<sub>2</sub> animals from a Berkshire/Yorkshire cross. See also Table 4 on page 48, which shows that the least square means for genotypes, wherein animals homozygous for 199(I) had higher pH values associated with better meat quality and. In addition, 199(I) was also associated with better meat color scores.

Applicants disclose in Provisional Application Serial No. 60/260,239 at page 19, 2<sup>nd</sup> full para. that "two different marker systems have been identified with high meat quality. One PRKAG3 marker system, PRKAG3-199 is found in the 1845 position of the PRKAG3 gene (codon 199) where the nucleotide carrying a guanine is changed to adenine. This mutation changes the amino acid valine to isoleucine in the peptide sequence (SEQ ID NO:2). The other PRKAG3 marker, PRKAG3-52 is found in the 154 position of the PRKAG3 (codon 52) where the nucleotide carrying a guanine is changed to adenine. Even more importantly, Applicants disclose that animals having either or both of these alleles potentially produce meat of the highest technical quality in terms of color, pH and drip loss. These polymorphisms can be used alone or in combination. (See page 20, 1<sup>st</sup> full para. Serial No. 60/260,239).

Applicants also respectfully direct Examiner's attention to page 22 of Provisional Application Serial No. 60/260,239, wherein a test for marker 199 shows that it was associated with higher pH, which is preferred with respect to meat quality. Further, on page 24, it is stated "the alleles 199I, from 199 locus, 52G from 52 locus and 30T from 30 locus were the favorable alleles in terms of meat quality." (See claim 45). The 199 mutation showed the highest association with meat quality traits. Also on page 35, Section V., of Provisional Application Serial No. 60/260,239, Applicants state that phenotypic measures were made for meat color and pH. Further, it is stated "the alleles 1 (I199) from 199 locus, 2 (G52) from 52 locus and 1 (T30) from 30 locus were the favorable alleles in terms of meat quality."

Additionally, Provisional Application Serial No. 60/299,111, at page 2, 2<sup>nd</sup> full para. states "prior to the work described in this application, there was no evidence for this gene influencing economic traits in other breeds. Surprisingly, new markers in the PRKAG3 gene, PRKAG3-199 and PRKAG3-52, have now been found to correlate with variation in meat quality traits...in many breeds of pigs other than the Hampshire breed. These new markers have been shown to correlate with meat with of the highest technical quality in terms of color, pH level, marbling, and drip loss and litter size." Association results are presented in Tables 3 and 4 pages 45 and 46, respectively.

At page 20, first full para., it is stated, in reference to PRKAG3-199 and PRKAG3-52, that "[a]nimals having either or both of these alleles potentially produce meat of the highest technical quality in terms of color, pH, and drip loss. These polymorphisms can be used alone or in combination. Most importantly, these polymorphisms are segregated in the breeds most commonly used for commercial pig meat production. Thus, this invention has a much broader application than the RN- test described by Milan et al. (2000), which is effectively limited to the Hampshire breed."

At page 23, 1<sup>st</sup> para., the Applicants state they have found alleles in the PRKAG3 "gene affecting glycogen content in muscle and in general the meat quality of pigs which includes, but is not limited to, ultimate pH, color, water holding capacity, drip loss, tenderness, and cooking loss."

Application Serial No. 60/299,111 discloses haplotype substitution effects wherein the traits measured are listed in Tables 3, 4, and 5 of 60/299,111. Also in F<sub>2</sub> association studies, 30T, 52G, and 199I alleles were favorable in terms of meat quality.

At page 31, 1<sup>st</sup> full para. haplotype 3 (30T-52G-199I) "was generally found to have the favorable effect (lower color scores)." (See claim 45). Also at page 31-Discussion-last para., it is disclosed that "the 199I mutation showed the most significant and largest differences in meat quality traits." Such traits listed are pH (Table 3) and meat color measures, wherein a lower color score is more favorable. At page 32, 2<sup>nd</sup> full para., haplotype 3 "which is the only

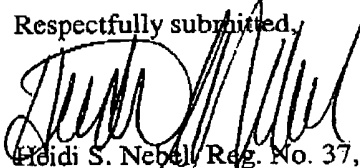
haplotype containing 199I, was the most favorable haplotype with respect to pH and meat color measurements." Applicants respectfully request reconsideration.

VI. CONCLUSION

Applicant is a large entity; therefore, please charge Deposit Account number 26-0084 in the amount of \$110 to cover a one month extension of time (March 19, 2004 to April 19, 2004). Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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